

64. (Once amended) The isolated polypeptide of claim 63 comprising the amino acid sequence shown as [residues 2 to 341 in]SEQ ID NO:2, but lacking the N-terminal methionine residue.

65. (Once amended) The isolated polypeptide of claim [64] 63 comprising the amino acid sequence shown as [residues 1 to 341 in]SEQ ID NO:2.

REMARKS

Claims 61(b), 64, and 65 were amended herein. Claims 1-60 were canceled previously. Accordingly, claims 61-77 are pending. Reconsideration of the objections and rejections made in the Official action mailed October 14, 1998 is respectfully requested in light of both the Amendment filed March 15, 1999 and the present Amendment.

I. Amendments

A substitute sequence listing and substitute Figures 1 and 3 are submitted herewith to correct nucleotide and amino acid sequence errors as originally presented in the ICE-LAP 3 sequences (shown in the sequence listing as SEQ ID NOS:1 and 2). These changes do not introduce new matter because the correct sequence was inherent to the originally sequenced plasmid clone in actual possession of the Applicants before the time the captioned application was filed.

The captioned application is directed to both polynucleotides and polypeptides which are chemical compounds. The nucleotide sequence is but an inherent property of the described polynucleotides. There is a line of chemical case law where applicants have been permitted to amend the specification to correct the formula of a chemical compound after an application's filing date, provided that it had been demonstrated that one of skill in the art would have appreciated that the applicant was in possession of the compound itself at the time of filing. The rationale is that the formula is an inherent property of the compound and thus amending the specification to correct the formula is not new matter. See *In re Nathan*, 140 U.S.P.Q. 601, 604 (C.C.P.A. 1964). Accord *Kennecott Corp. v. Kyocera Int'l, Inc.*, 5 U.S.P.Q.2d 1194, 1198 (Fed. Cir. 1987), cert. denied, 486 U.S. 1008 (1988) ("The disclosure in a subsequent patent application of an inherent property of a product does not deprive that product of the benefit of the earlier filing date.").

In the field of biotechnology, applicants often rely on a deposited clone, where the deposit was made prior to filing, to establish possession of nucleic acids or proteins. The focus for determining whether applicants were in possession of claimed nucleic acids or proteins has been determined, at least in part, by considering whether the applicant has: (1) established that one skilled in the art in possession of the deposited clone would have been aware of both the

DNA sequence and the encoded amino acid sequence, or would be able to determine these sequences without undue experimentation, (2) established that the DNA and amino acid sequences are described in a manner such that one skilled in the art could distinguish them from other sequences, and (3) resequenced a clone which is identical to that of the deposit and established a "chain of custody" for this clone. See e.g., *Ex parte Maizel*, 27 U.S.P.Q.2d 1662, 1669-1670 (B.P.A.I. 1992).

Submitted herewith is a Declaration of Craig Rosen Under 37 CFR §1.132 (the "Rosen Declaration") which describes certain events involving the characterization of the nucleotide sequence of cDNA clone HE2CA82 which encodes ICE-LAP 3. The HE2CA82 cDNA clone was deposited with the American Type Culture Collection (ATCC) on August 25, 1994; i.e., prior to the filing date of parent application US Serial No. 08/334,251 (filed November 1, 1994). Exhibit A of the Rosen Declaration is a copy of the contract for ATCC Deposit No. 75875. The Examiner will note that the present specification states on page 5, lines 7 and 8, that ATCC Deposit No. 75875 contains the cDNA which encodes ICE-LAP 3.

The corrected nucleic acid and deduced amino acid sequences (shown in replacement Figures 1 and 3 submitted herewith) were determined by reanalyzing cDNA clone HE2CA82 (ATCC Accession No. 75875); i.e., the same cDNA clone from which the originally presented sequences were determined (see paragraph 4 of the Rosen Declaration). The corrected sequence information was published by the present inventors in a peer-reviewed scientific journal article (see Exhibit B of the Rosen Declaration).

The analysis needed to determine the complete and correct sequences of cDNA clone HE2CA82 were well within the skill of the ordinary artisan as of the filing date of the parent application US Serial No. 08/334,251 (filed November 1, 1994), and such analysis would not have required undue experimentation (see paragraph 5 of the Rosen Declaration).

Exhibit D of the Rosen Declaration shows the four (4) nucleotide differences between the original sequence ("PF140" in the Exhibit) and the corrected sequence ("Duan" in the Exhibit).

In summary, because Applicants have demonstrated that the corrected sequences are inherently present in the deposited material, and because Applicants have demonstrated "chain of custody" for the material originally sequenced and the resequenced material, correction of the originally presented sequence information herein is not new matter.

The specification was amended on page 5 to correct the location of the pentapeptide QACRG in SEQ ID NO:2.

The specification was further amended on page 5 to correct the spelling of "homolog".

Claims 61, 64, and 65 were amended herein. Support for the amended claims can be found in the specification and claims as originally filed. In particular, support for claims 61(b) and 64 which recite a polypeptide "lacking an N-terminal methionine residue" can be found in the specification, for example, on page 17, lines 32 and 33.

Accordingly, no new matter has been added herein.

VII. Summary

Applicants believe that the application is in condition for allowance and a notice to that effect is earnestly solicited. If the Examiner believes that a telephone conference would help to facilitate prosecution of the present application she is encouraged to call Applicants' representative at the telephone number listed below.

Respectfully submitted,

Dated: 3/22/99

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